

(19) World Intellectual Property
Organization
International Bureau



549403

(43) International Publication Date
23 September 2004 (23.09.2004)

PCT

(10) International Publication Number
WO 2004/081528 A2

(51) International Patent Classification⁷: **G01N**
(21) International Application Number:
PCT/US2004/007231
(22) International Filing Date: 9 March 2004 (09.03.2004)
(25) Filing Language: English
(26) Publication Language: English
(30) Priority Data:
60/455,029 10 March 2003 (10.03.2003) US
60/453,741 11 March 2003 (11.03.2003) US
60/453,977 12 March 2003 (12.03.2003) US

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(71) Applicants and
(72) Inventors: **ROBINSON, Joseph, R.** [—/US]; P.O. Box 5257, New York, NY 10150-5257 (US). **ZIN, Benedict, L.** [US/US]; Mizuho USA, Inc., 1231 Community Road, Poway, CA (US).

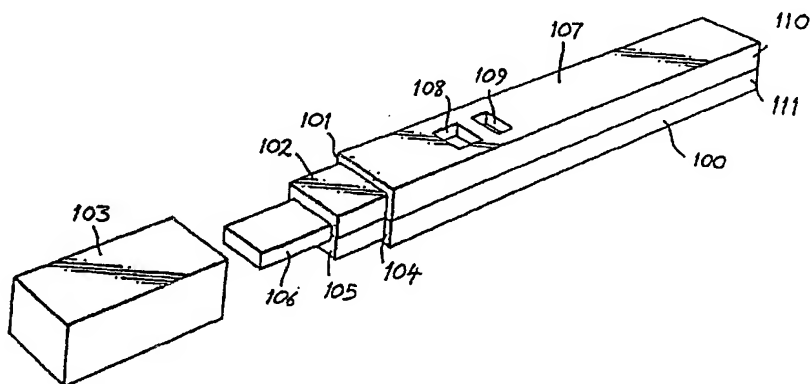
(74) Common Representative: **ROBINSON, Joseph, R.**, et al.; Darby & Darby P.C., P.O. Box 5257, New York, NY 10150-5257 (US).

Published:

— *without international search report and to be republished upon receipt of that report*

[Continued on next page]

(54) Title: ASSAY DEVICE AND METHOD



(57) Abstract: The present invention provides a test device for detecting the presence or absence of a selected analyte in a liquid sample. The test device includes a reagent member, a porous carrier, and a detection zone. The reagent member includes a body, a first labeled binding reagent specific for a first binding site of the analyte and a second labeled binding reagent specific for a second binding site of the analyte. The first specific binding site and second binding sites are different. The reagent body is adapted to retain the first and second labeled specific binding reagents when the body and the first and second labeled binding reagents are dry, and to release them when the body and they are moist. The first and second labeled specific binding reagents are capable of forming a first labeled complex with the analyte with the complex including the first labeled specific binding reagent, the analyte, and the second labeled specific binding reagent. The detection zone includes a first porous barrier having an average pore size larger than the diameter of the larger diameter of the first or second labeled specific binding reagent, but smaller than the diameter of the first with the porous carrier. The detection zone may be a section of the porous carrier or may be separate from and in fluid communication would travel sequentially from the reagent member to the porous carrier and to the detection zone. The test device is typically dry before use and moist during use.

WO 2004/081528 A2



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.